Healthy Learning Mind - Effectiveness of a mindfulness program on mental health compared to a relaxation program and teaching as usual in schools: a cluster-randomised controlled trial

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Research paper

Healthy learning mind – Effectiveness of a mindfulness program on mental health compared to a relaxation program and teaching as usual in schools: A cluster-randomised controlled trial

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ABSTRACT

Background: Mindfulness-Based Interventions (MBIs) have shown promising effects on mental health among children and adolescents, but high-quality studies examining the topic are lacking. The present study assessed the effects of MBI on mental health in school-setting in an extensive randomised controlled trial.
Methods: Finnish school children and adolescents (N = 3519), aged 12–15 years (6th to 8th graders), from 56 schools were randomized into a 9 week MBI group, and control groups with a relaxation program or teaching as usual. The primary outcomes were resilience, socio-emotional functioning, and depressive symptoms at baseline, at completion of the programs at 9 weeks (T9), and at follow-up at 26 weeks (T26).
Results: Overall, mindfulness did not show more beneficial effects on the primary outcomes compared to the controls except for resilience for which a positive intervention effect was found at T9 in all participants ($\beta = 1.18$, SE 0.57, p = 0.04) as compared to the relaxation group. In addition, in gender and grade related analyses, MBI lowered depressive symptoms in girls at T26 ($\beta = -0.49$, SE 0.21, p = 0.02) and improved socio-emotional functioning at T9 ($\beta = -1.37$, SE 0.69, p = 0.049) and at T26 ($\beta = -1.71$, SE 0.73, p = 0.02) among 7th graders as compared to relaxation.
Limitations: The inactive control group was smaller than the intervention and active control groups, reducing statistical power.
Conclusions: A short 9-week MBI in school-setting provides slight benefits over a relaxation program and teaching as usual. Future research should investigate whether embedding regular mindfulness-based practice in curriculums could intensify the effects.

1. Introduction

Important mental health and social problems often start or peak in early adolescence through to young adulthood (World Health Organisation, 2017). In Finland, approximately 14% of children aged 8–9 years suffer from some kind of mental health problems, and the proportion steeply arises with the onset of puberty to 15–25% in adolescent and young adult population (Kinnunen et al., 2010). Psychiatric disorders are the most usual reason that impairs adolescents' performance, such as educational achievements (Patel et al., 2007).

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The application of Mindfulness-Based Interventions (MBI) in schools has become increasingly popular in the last few years, and programmes, interventions, and accompanying research on MBI in school context are increasing exponentially. Mindfulness can be defined as the psychological capacity to stay willingly present with one's experiences, with a non-judging or accepting attitude, engendering a warm and friendly openness and curiosity (Kabat-Zinn, 2005). The core idea of mindfulness training is attending, observing, and accepting, what is happening here-and-now, involving a continuous attention to both outer events and inner experience in a purposeful way without judgement or criticism (Meiklejohn et al., 2012). Despite the extensive research on mindfulness in school context, there are no robust RCT's grounded in the theory and using an adequate follow-up period that have evaluated the benefits of MBI across the whole spectrum of risk/resilience in children and adolescents (Kuyken et al., 2017).

Recent systematic reviews and meta-analyses of studies conducted in school settings have shown MBIs to be popular among staff and students, and found little evidence of adverse effects from these interventions (Weare, 2018). A systematic review and meta-analysis by Zenner et al. (2014) showed that MBI induced effects in the school context are seen mostly in the cognitive domain, but also in psychological measures of stress, coping, and resilience. The effect has been stronger with increasing frequency of mindfulness training and mindfulness practice at home. Of the 24 studies included, 19 used a controlled design, of which few were randomized. Additionally, reliable conclusions of the effects of mindfulness cannot be drawn due to e.g., heterogeneity and unpowered data sets (Zenner et al., 2014). Felver et al. (2016) showed in their systematic review on MBI in school settings that half of the studies lacked any type of comparative design. Their review showed that MBIs was associated with decreased prevalence of behavioral problems and depression (Felver et al., 2016) with almost twice the general effect size compared with other outcomes (Zoogman et al., 2014). Carsley et al. (2018) reviewed 24 studies and reported small to moderate effects from pre-post MBI compared to control groups. However, less than half of those studies included active controls; also sample sizes remained quite low. Black (2016) reviewed 40 MBI studies conducted in school and clinical settings. Based on results from randomized controlled trials, Black (2016) draw a conclusion of MBI to be “probably efficacious” for reducing anxiety and depression and improving physiological indices of stress (e.g., heart rate, blood pressure). Klingbeil et al. (2017) reviewed 76 MBI studies across school and non-school settings, with clinical and non-clinical samples (of which 46% RCTs). Their main conclusions were that MBIs have small, positive therapeutic effects across a variety of youth outcome domains (Klingbeil et al., 2017).

These above-mentioned findings have not been demonstrated in large-scale randomized controlled trials (RCT) and methodological problems may have overestimated the benefits of MBI. Moreover, the positive aspects of psychological functioning have been less consistently demonstrated in previous studies (Tan, 2016) with modest effect sizes (Zoogman et al., 2014). Thus, resilience, which has been linked to mindfulness training and its benefits, would be an outcome worth exploring (Zong-Kui et al., 2017).

2. The present study

The Healthy Learning Mind (HLM) study is, to our knowledge, the first RCT to evaluate the specific effects of a mindfulness-based program in school-setting with a comparison program of equal dose and comparable didactic and experiential content as recommended in previous research (Felver et al., 2016).

The aims of this study were to compare the effects of MBI (Stop and Breathe/Be .b) at 9 weeks, i.e., at the completion of the program, and at 6 month follow-up, i.e., 26 weeks from the baseline with a standard relaxation program ‘Relax’(active controls) and teaching as usual (inactive controls) in school context among 12–15 year old pupils. We assessed these effects in three primary outcomes; resilience (i.e., the capacity to recover from difficulties), socio-emotional functioning (i.e., experienced psychological strengths and difficulties), and depressive symptoms (existence or absence of depressive symptoms). These three main outcomes were chosen since they all were assessed to be important in either producing or threatening the well-being and learning of children and adolescents. We also explored the effects of age (=grade) and gender on the outcomes and the potential effect of the independent mindfulness-practice within the intervention group, as has been called for (Carsley et al., 2018).

3. Methods

3.1. Trial design

The study is a cluster RCT with three study arms (retrospective registration: ISRCTN18642659). Eligible schools were randomly allocated to an intervention group and to an active control or an inactive control groups (Volanen et al., 2016).

3.2. Participants

Recruitment began in 2013 by listing all the 247 schools in 14 cities/municipalities in Southern Finland of which 56 (24%) participated (Fig. 1). The most frequent reasons for non-participating were: (1) principal was not reached during the recruitment period (25%); (2) school was already participating in other research or development projects (23%); (3) there were not enough interested teachers in the school to join (18%); and 4) other (11%). Participants were sixth, seventh, and eighth graders (age 12–15) in Finnish comprehensive school. Students, who were randomized to intervention group had high participation percentage: Out of nine mindfulness lessons, in all, 90% of students took part in 7–9 lessons, 5% took part in 6 lessons, and 5% took part in 1–5 lessons.

Data collection commenced in March 2014, and finished in December 2016. Data analyses started in January 2017.

3.3. Procedure

The ethical review board of the University of Helsinki, (approval 1/2014) reviewed the study plan. A written informed consent was requested from all participants and their parents, and the study was conducted according to the Helsinki Declaration. Data handling and analyses were performed according to the Finnish data protection act, and personal identification of the participants is not possible.

The schools were randomly assigned to MBI schools ($N = 94$ classes), active control schools ($N = 85$ classes), and inactive control schools ($N = 31$ classes). First, the schools were divided into three groups based on school location and the average apartment price per square meter, to account for socioeconomic differences (Volanen et al., 2016). An experienced statistician (A.B.) generated the random allocation sequence implemented by the project team. For the details of the study design, please see the RCT protocol (Volanen et al., 2016).

3.4. Intervention

The intervention, 9-week mindfulness-program .b (Stop and Breathe/Be) (Huppert and Johnson, 2010) began after baseline (T0) measurements. The .b-program includes nine weekly 45-min group sessions and short home practices (the recommended amount of practice being 5–6 times per week, approx. 3–15 min at a time) and designed to improve emotional awareness, sustained attention, and attentional and emotional regulation. Preliminary research suggest it to be effective in decreasing depressive symptoms, lowering stress and enhancing psychological well-being (Kuyken et al., 2013) (https://mindfulnessinschools.org/teach-dot-b/dot-b-curriculum/). Trained and

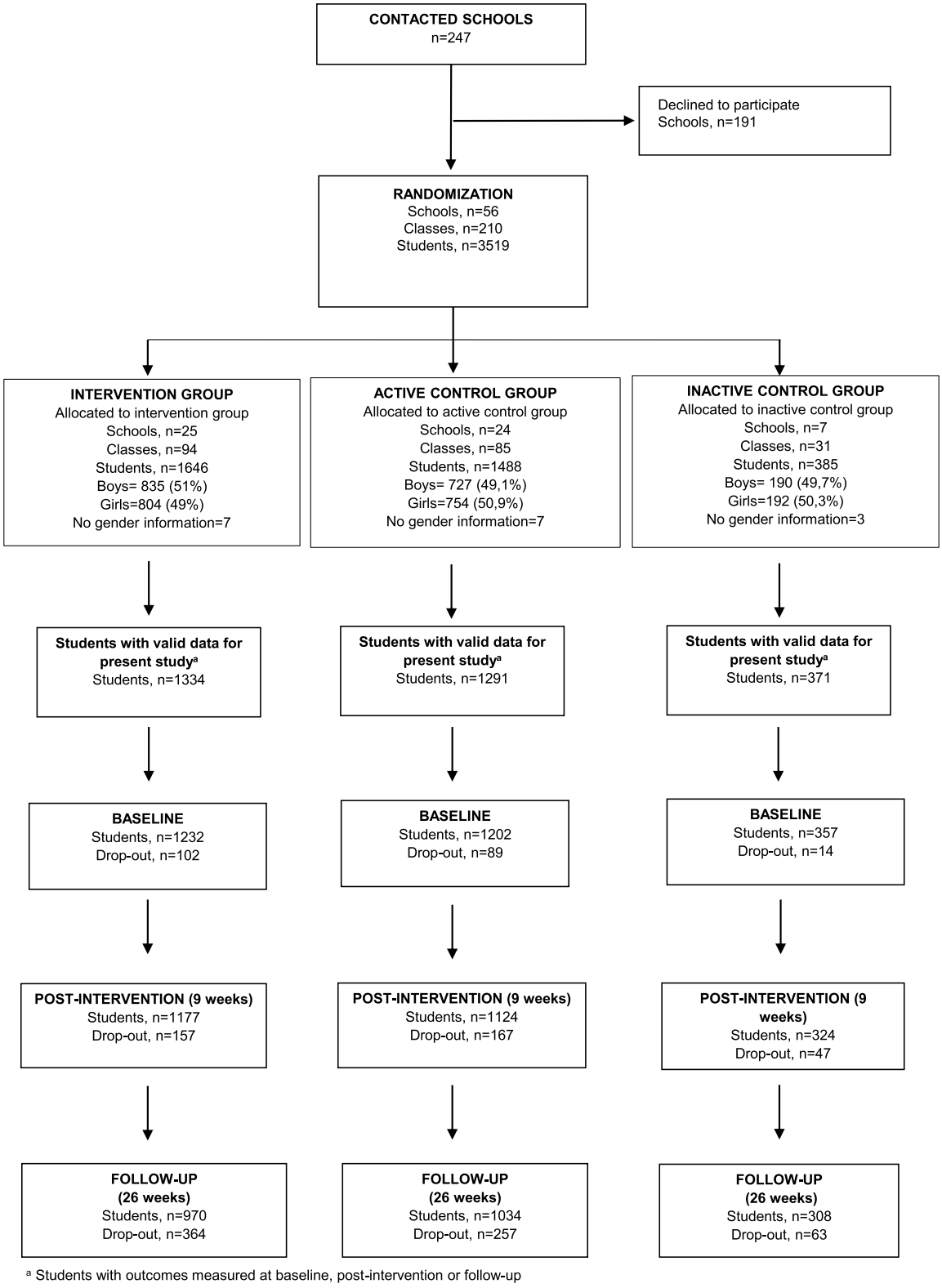

Fig. 1. Flowchart of participants.

certified mindfulness facilitators with years of established mindfulness meditation practice delivered the .b-intervention in classes.

3.5. Control groups

Active control group underwent a 9-week standardized relaxation program 'Relax' after baseline (T0) measurements. The aim of the Relax-program is to enhance relaxation skills and holistic well-being. The frequency and duration of the weekly sessions (i.e., dose) of the Relax-program is equal to the .b program including nine weekly 45 min group sessions and home practices (the recommended amount of practice being 5–6 times per week). The control program was focusing on e.g. stress management, sleep, screen time, and experiential relaxation practices, lasting a few minutes. All Relax facilitators were

either certified school teachers, or experienced leaders of well-being groups among this age group. Special attention was paid to not bringing in any mindfulness elements in the control program. For details, we refer to the protocol (Volanen et al., 2016).

In the inactive control group, the participants followed the usual school curriculum without any interventions. Both active and inactive control groups completed the same research questionnaires as the intervention group, at baseline (T0), at completion of the program (at 9 weeks, T9), and at follow-up 6 months after the program (26 weeks from the baseline, T26).

3.6. Blinding

Classes in the intervention and in the active control groups were informed about participation in a 9-week program called 'Skills for Wellbeing'.

3.7. Primary outcomes

Three primary outcomes were chosen to build on previous research of MBIs among young people, and to explore the connections between mindfulness and other psychological functions that contribute to well-being.

The Resilience scale (RS14) was employed to measure resilience (Wagnild and Young, 1993). RS14 consists of 14 self-report-items measured on a 7-point likert scale from 1 (strongly disagree) to 7 (strongly agree; score range 14–98). A higher score for RS14 indicates more resilience. Baseline Cronbach's alpha coefficient of RS14 was 0.87.

The Beck Depression Inventory (RBDI) (Beck et al., 1988; Raitasalo, 2007) was used to measure level of depressive symptoms. Raitasalo's modification of the short form of the Beck Depression Inventory is well established in screening adolescent samples in Finland (Kaltiala-Heino et al., 1999). Due to ethical reasons, the item concerning suicidal ideation was removed and a 12-item version of RBDI corresponding psychometrically to the original 13-item version was used (Kosunen et al., 2003). Each item is scored 0–3 according to the severity of the symptom and RBDI was calculated as the sum score of the 12 items (range 0–36). Lower score for RBDI indicates less depression symptoms. Baseline Cronbach's alpha coefficient of RBDI was 0.86.

The Strengths and difficulties questionnaire (SDQ) (Goodman, 1997, 2001) was used to measure socio-emotional functioning. SDQ includes 25 items scored 0 (not true), 1 (somewhat true) and 2 (certainly true). The symptom part comprises 10 positive and 15 negative statements forming five subscales: emotional problems, conduct problems, hyperactivity, peer problems and pro-sociality. The scores of all subscales, except the pro-sociality scale, are summed up to calculate a total socio-emotional functioning score (range 0–40). Lower score for SDQ indicates better socio-emotional functioning. Baseline Cronbach's alpha coefficient of SDQ was 0.79 (Goodman, 1997, 2001).

3.8. Statistical analysis

Based on power calculations, the study required 1200 participants in both intervention and active control groups and 540 participants in the inactive control group. Sample size was smaller in the inactive control group because we expected larger effect size when comparing intervention group to inactive control group. For details, please see the protocol (Volanen et al., 2016). All analyses (overall intervention effect and subgroup analyses) were pre-specified in the protocol and based on intention to treat principle, expect one additional per protocol analysis in order to explore the effect of the continuing independent practice intensity. Interaction analyses (group × grade, group × gender and group × practice intensity) and further subgroup analyses (by grade, gender and practice intensity) were exploratory in nature.

The effect of intervention on resilience, depression, and socio-emotional functioning was analysed with multilevel models to account for the clustered nature of the data. Four-level models with time at level 1, student at level 2, students in a particular classroom at level 3, and school at level 4 were fitted. Intra-class correlation (ICC), which is the proportion of the total variance explained by each level, were calculated to examine the intra-class correlations between students, classrooms, and schools. ICCs at the school level were low and non-significant for all three outcomes (ICC < 0.01). Thus, school-level variance was excluded from the final multilevel models and a three-level model with time at level 1, student at level 2, and classroom at level 3 were used. In addition to variance components at the classroom level and student level, the covariance between random components were also included in the models (not shown in the tables), if estimable. Maximum likelihood estimation was used to obtain unbiased and efficient parameter estimates for data with missing values in the follow-up measurements.

Multilevel linear models included the main effects of group, time, gender, and grade (=age). The intervention effect was examined by interaction terms between group (intervention vs. active control and intervention vs. inactive control) and time (9 weeks vs. baseline and 26 weeks vs. baseline). To show positive intervention effects the estimates for interaction effects (Group × T9 and Group × T26) were required to be positive for resilience and negative for depression symptoms and socio-emotional functioning. Interaction effects indicated the change in outcomes between the intervention group compared to the active control and inactive control groups. To analyse the modifying effect of grade and gender, i.e., whether the intervention effect (intervention vs. active control and intervention vs. inactive control) was different depending on grade or gender, the second-order interaction term group × grade × time or group × gender × time was entered to the model. To examine whether the intervention effect differed depending on the continuing independent practice intensity after the intervention (a couple of times in 6 months, once/twice a month, at least once a week, nearly every day), the interaction term practice intensity × time was entered to the model. Analyses were performed for all students and separately for boys and girls.

Multilevel linear modelling was done with MLwiN Version 2.35 (Centre for multilevel modelling, University of Bristol) and other analysis with the SAS System for Windows 9.4 (SAS Institute Inc., Cary, NC). Two-sided statistical tests with a 5% significance level were used, and no adjustments were made for multiplicity.

4. Results

4.1. Sample characteristics

There were a total of 3519 students participating in the study (Fig. 1 and online Supplementary Table S1). Altogether 2996 students provided at least one measurement at T0, T9, or T26 on any of the main outcome variables resilience, depressive symptoms, and socio-emotional functioning, and were included in statistical analysis. The descriptive statistics for outcome variables are presented in Table 1.

ICCs at the classroom level for resilience, depressive symptoms, and socio-emotional functioning were 0.03, 0.02, and 0.06, respectively. ICCs at the student level for resilience, depressive symptoms, and socio-emotional functioning were 0.57, 0.64, and 0.66.

4.2. Baseline position

Intervention and active or inactive control groups did not differ in main outcomes of resilience, depression, and socio-emotional functioning at T0 (Tables 2–4). Among boys, however, depression symptoms were higher in the intervention group compared to the inactive control group (Table 4, $\beta = 0.64$, $p = 0.04$). All boys combined had less depression symptoms than girls combined (Table 2, $\beta = -1.02$, $p < 0.001$). Eighth grade (approximately 14 years old) students had lower resilience (Table 3, for girls $\beta = -1.51$, $p = 0.046$), experienced higher symptoms

Table 1
Descriptive statistics for outcome variables RS14, RBDI and SDQ at baseline (T0), nine weeks (T9) and 26 weeks (T26) for all students and by gender.

Variable	Intervention group						Active Control group						Inactive control group					
	N	T0 Mean (SD)	N	T9 Mean (SD)	N	T26 Mean (SD)	N	T0 Mean (SD)	N	T9 Mean (SD)	N	T26 Mean (SD)	N	T0 Mean (SD)	N	T9 Mean (SD)	N	T26 Mean (SD)
All students																		
RS14	1228	77.093 (11.347)	1175	76.864 (12.150)	966	77.218 (13.168)	1196	76.992 (11.153)	1114	75.512 (12.624)	1030	76.913 (13.597)	356	76.814 (10.825)	323	77.349 (13.094)	307	76.907 (11.832)
RBDI	1162	2.174 (4.024)	1120	1.934 (3.910)	934	1.805 (3.651)	1141	2.097 (3.747)	1054	1.971 (3.597)	966	1.966 (4.232)	339	2.174 (4.138)	318	1.944 (4.110)	304	2.007 (4.232)
SDQ	1219	10.403 (5.442)	1157	10.099 (5.850)	947	9.812 (5.867)	1168	10.199 (5.446)	1101	10.398 (6.078)	1014	9.743 (6.112)	350	10.323 (5.536)	318	10.035 (5.963)	302	9.752 (5.916)
Boys																		
RS14	618	77.389 (11.107)	573	77.035 (12.874)	471	76.223 (14.565)	574	77.003 (10.952)	522	75.446 (13.335)	490	76.450 (14.353)	173	76.654 (10.409)	154	78.370 (12.940)	151	77.077 (11.449)
RBDI	567	1.708 (3.648)	535	1.443 (3.438)	450	1.640 (3.913)	531	1.566 (3.262)	476	1.396 (2.855)	449	1.462 (3.933)	161	1.055 (2.029)	148	1.090 (2.750)	149	1.218 (3.591)
SDQ	613	10.326 (5.611)	564	10.348 (6.245)	460	10.402 (6.394)	556	10.228 (5.640)	511	10.906 (6.568)	482	10.071 (6.341)	170	9.759 (5.556)	151	9.311 (5.922)	149	9.369 (5.947)
Girls																		
RS14	610	76.793 (11.587)	601	76.713 (11.433)	495	78.165 (11.620)	622	76.983 (11.343)	591	75.674 (11.712)	540	77.333 (12.873)	183	76.965 (11.230)	169	76.420 (13.202)	155	76.722 (12.263)
RBDI	595	2.618 (4.308)	584	2.387 (4.252)	484	1.958 (3.386)	610	2.559 (4.070)	577	2.448 (4.053)	517	2.404 (4.434)	178	3.187 (5.178)	170	2.688 (4.890)	154	2.769 (4.669)
SDQ	606	10.480 (5.270)	592	9.846 (5.432)	487	9.255 (5.268)	612	10.173 (5.268)	589	9.924 (5.530)	532	9.445 (5.887)	180	10.856 (5.478)	167	10.689 (5.942)	152	10.059 (5.846)

of depression (Table 2, for all students $\beta = 0.53$, $p = 0.002$; Table 3 for girls $\beta = 1.04$, $p < 0.001$) and showed poorer socio-emotional functioning (Table 2 for all students $\beta = 1.13$, $p < 0.001$, Table 3 for girls $\beta = 1.71$, $p < 0.001$) as compared to sixth-grade (approximately 12 years old) students at the baseline.

4.3. Overall intervention effects among all students

Positive intervention effect was found for resilience at T9 between intervention and the active control group (Table 2, Group × T9, $\beta = 1.183$, $p = 0.038$). Resilience remained at the same level in the intervention group and decreased in the active control group at T9.

4.4. Intervention effects by grade

Grade modified the intervention effects on socio-emotional functioning (Models 2, Table 2). The effect of the intervention was significantly different between sixth and seventh grades (i.e., approximately 12–13years olds) at T9 (Table 2, Group × Grade7 × T9, $\beta = -1.44$, $p = 0.04$) and marginally different between sixth and seventh grades at T26 (Table 2, Group × Grade7 × T26, $\beta = -1.58$, $p = 0.07$) and between sixth and eighth grades (i.e., approximately 12–14years olds) (Table 2, Group × Grade8 × T26, $\beta = -1.08$, $p = 0.06$) compared to the active control group. Separate models for each grade were fitted to examine interactions. These models showed significant positive intervention effects for socio-emotional functioning among seventh graders' (approximately 13 years olds') in the intervention group at T9 and T26 (Group × T9, $\beta = -1.37$, $p = 0.049$ and Group × T26, $\beta = -1.71$, $p = 0.02$) compared to the active control group.

The intervention effect on resilience was marginally different between sixth and seventh grades (approximately 12–13years olds) at T9 favouring the latter compared to the inactive control group among all students (Table 2, Group × Grade7 × T9, $\beta = 4.13$, $p = 0.05$).

4.5. Intervention effects by gender

Gender modified the intervention effects on resilience and socio-emotional functioning. The intervention effect on resilience was significantly different between girls and boys at T9 (Group × Girls × T9, $\beta = 2.92$, $p = 0.03$) and at T26 (Group × Girls × T26, $\beta = 3.30$, $p = 0.03$) and marginally different on socio-emotional functioning between girls and boys at T26 (Group × Girls × T26, $\beta = -1.19$, $p = 0.07$) compared to the inactive control group.

Among girls, a significant positive intervention effect was found for resilience at T9 (Table 3, Group × T9, $\beta = 1.30$, $p = 0.03$) and for depression at T26 (Table 3, Group × T26, $\beta = -0.49$, $p = 0.02$) in follow-up between the intervention and the active control group. Resilience remained at the same level in the intervention group and decreased in the active control group, while depression was alleviated in the intervention group and did not change in the active control group. The intervention also had a marginally favourable effect on depression symptoms at T9 (Table 3, Group × T9, $\beta = -0.31$, $p = 0.09$) among girls. Among boys, no intervention effects were detected.

Among girls, marginally modifying effects of grade on intervention effect on socio-emotional functioning were found between sixth and seventh grades (approximately 12–13years olds) at T9 (Table 3, Group × Grade7 × T9, $\beta = -1.36$, $p = 0.08$), and a significant modifying effect between sixth and eighth grades (Table 3, Group × Grade8 × T26, $\beta = -1.32$, $p = 0.04$) compared to the active control group. Among boys, a corresponding marginally modifying effect of grade was seen between sixth and seventh grades (approximately 12–13 years olds) at T26 (Table 4, Group × Grade7 × T26, $\beta = -2.26$, $p = 0.097$).

The intervention effect on resilience was marginally different between sixth and seventh grades at T9 compared to the active control

Table 2
Results of multilevel models: Intervention effects (Model 1) on resilience (RS14), depression (RBDI) and social/emotional/behavioural skills (SDQ) and modifying effect of grade on intervention effectiveness (Model 2) among all students.

	RS14		RBDI		SDQ	
	Model 1 Estimate (SE)	Model 2 Estimate (SE)	Model 1 Estimate (SE)	Model 2 Estimate (SE)	Model 1 Estimate (SE)	Model 2 Estimate (SE)
Baseline						
Intercept	**77.407 (0.566)**	**78.078 (0.702)**	**2.395 (0.170)**	**2.408 (0.212)**	**9.752 (0.276)**	**9.594 (0.331)**
Grade 7 vs. 6	0.478 (0.721)	−1.741 (1.310)	0.189 (0.218)	0.375 (0.394)	0.136 (0.374)	0.461 (0.612)
Grade 8 vs. 6	−0.936 (0.551)	−1.715 (0.899)	**0.525 (0.166)**	0.441 (0.269)	**1.134 (0.287)**	**1.376 (0.422)**
Boys vs. girls	0.034 (0.381)	0.035 (0.381)	**−1.019 (0.129)**	**−1.013 (0.129)**	0.258 (0.187)	0.259 (0.187)
Group (Int vs. 0)	0.624 (0.898)	1.736 (1.503)	0.011 (0.268)	−0.121 (0.457)	−0.107 (0.425)	0.085 (0.714)
Group (Int vs. Control)	0.267 (0.602)	1.611 (0.981)	0.078 (0.178)	0.235 (0.293)	0.064 (0.282)	−0.410 (0.462)
Group (Int vs. 0) × Grade (7 vs. 6)		−2.990 (2.216)		0.442 (0.670)		−0.554 (1.045)
Group (Int vs. Control) × Grade (7 vs. 6)		−2.405 (1.824)		0.086 (0.549)		0.945 (0.855)
Group (Int vs. 0) × Grade (8 vs. 6)		−1.271 (2.189)		0.064 (0.662)		0.294 (1.035)
Group (Int vs. Control) × Grade (8 vs. 6)		−2.101 (1.297)		−0.340 (0.387)		0.679 (0.610)
Change by 9 weeks						
T9	−0.415 (0.399)	−0.731 (0.629)	**−0.217 (0.094)**	−0.167 (0.151)	−0.117 (0.161)	0.007 (0.250)
Group (Int vs. 0) × T9	−1.135 (0.837)	−2.525 (1.481)	−0.006 (0.198)	−0.068 (0.362)	0.066 (0.341)	−0.838 (0.599)
Group (Int vs. Control) × T9	**1.183 (0.570)**	0.411 (0.911)	−0.140 (0.135)	−0.054 (0.219)	−0.419 (0.231)	−0.012 (0.364)
Grade (7 vs. 6) × T9		2.385 (1.240)		0.035 (0.303)		−0.650 (0.497)
Grade (8 vs. 6) × T9		−0.009 (0.843)		−0.113 (0.203)		−0.084 (0.336)
Group (Int vs. 0) × Grade (7 vs. 6) × T9		4.132 (2.127)		0.270 (0.518)		0.819 (0.856)
Group (Int vs. Control) × Grade (7 vs. 6) × T9		1.732 (1.735)		−0.173 (0.424)		**−1.439 (0.697)**
Group (Int vs. 0) × Grade (8 vs. 6) × T9		1.040 (2.102)		−0.093 (0.510)		1.328 (0.849)
Group (Int vs. Control) × Grade (8 vs. 6) × T9		1.127 (1.214)		−0.128 (0.293)		−0.410 (0.486)
Change by 26 weeks						
T26	−0.190 (0.398)	−0.770 (0.618)	**−0.286 (0.137)**	−0.227 (0.220)	−0.341 (0.197)	−0.267 (0.303)
Group (Int vs. 0) × T26	−0.441 (0.813)	−0.332 (1.503)	−0.231 (0.274)	−0.261 (0.504)	0.181 (0.395)	−0.224 (0.699)
Group (Int vs. Control) × T26	0.132 (0.558)	−0.953 (0.884)	−0.286 (0.193)	−0.405 (0.315)	−0.178 (0.276)	0.529 (0.434)
Grade (7 vs. 6) × T26		**2.894 (1.325)**		0.027 (0.480)		−1.240 (0.665)
Grade (8 vs. 6) × T26		0.493 (0.826)		−0.113 (0.289)		0.091 (0.399)
Group (Int vs. 0) × Grade (7 vs. 6) × T26		1.935 (2.170)		0.084 (0.749)		−0.456 (1.040)
Group (Int vs. Control) × Grade (7 vs. 6) × T26		2.264 (1.737)		0.594 (0.624)		−1.584 (0.859)
Group (Int vs. 0) × Grade (8 vs. 6) × T26		−0.059 (2.047)		0.098 (0.693)		0.626 (0.961)
Group (Int vs. Control) × Grade (8 vs. 6) × T26		1.778 (1.178)		0.058 (0.414)		−1.080 (0.570)
Variance components						
Student level						
Intercept	**80.211 (2.851)**	**80.179 (2.850)**	**9.625 (0.324)**	**9.625 (0.324)**	**20.579 (0.679)**	**20.553 (0.679)**
T9	**18.076 (3.636)**	**18.049 (3.636)**	0.000* (0.000*)	0.000* (0.000*)	**2.556 (0.703)**	**2.542 (0.704)**
T26	**42.229 (4.161)**	**42.166 (4.160)**	**2.580 (0.344)**	**2.586 (0.344)**	**4.714 (0.746)**	**4.716 (0.747)**
Classroom level						
Intercept	**6.117 (1.516)**	**5.669 (1.467)**	**0.294 (0.114)**	**0.287 (0.113)**	**1.243 (0.334)**	**1.155 (0.324)**
T9	**4.854 (1.347)**	**4.287 (1.285)**	0.000* (0.000*)	0.000* (0.000*)	**0.595 (0.220)**	**0.459 (0.204)**
T26	1.936 (1.249)	1.300 (1.173)	**0.393 (0.128)**	**0.361 (0.125)**	**1.050 (0.303)**	**0.772 (0.271)**

Statistically significant ($p < 0.05$) estimates from Wald tests are bolded.
Int = Intervention group (n = 1334).
Cont = Active control group (n = 1291).
0 = Inactive control group (n = 371).
* Due to convergence problems, the variance was fixed to zero.

group among girls (Table 3, Group × Grade7 × T9, $\beta = 3.15$, $p = 0.09$).

4.6. Intervention effects of continuing independent home practice after the intervention

The modifying effect of continuing practice after the intervention was examined by interaction term between independent practice group and time (online Supplementary Table S2) with an additional exploratory per protocol analysis. The intervention was effective in the high intensity practice group among the students who had practiced mindfulness nearly every day (n = 43) compared to the all students in the active and inactive control groups. There was a clear trend of the highest intensity practice group having greater increase in resilience compared to all students within the active control group (online Supplementary Table S2, Group × T9, $\beta = 3.26$, $p = 0.06$, Group × T26, $\beta = 3.95$, $p = 0.03$) and in the inactive control group (online Supplementary Table S2, Group × T26, $\beta = 3.30$, $p = 0.07$). There was more improvement in socio-emotional functioning in the highest intervention intensity group compared to all other students in the active control group and in the inactive control group at T9 (online Supplementary Table S2, Group × T9, $\beta = -2.22$, $p = 0.004$ and Group × T9, $\beta = -1.79$, $p = 0.03$) and marginally more improvement compared to the active control group at T26 (online Supplementary Table S2, Group × T26, $\beta = -1.33$, $p = 0.08$).

4.7. Effect sizes

The intervention effect sizes (Cohen's d) are presented in online Supplementary Table S3. Cohen $d = 0.2$ is considered as a small effect size, and Cohen $d = 0.5$ as a medium effect size. The largest intervention effects on resilience were seen in the highest intensity practice group at T9 (0.29) and T26 (0.35) compared to the active control and at T26 (0.30) compared to the inactive control group.

The intervention increased socio-emotional functioning in seventh graders (approximately 13 years olds) at T9 (−0.25) and T26 (−0.31) compared to the active control group. Intervention was effective among seventh graders (13 years olds) at T26 (−0.22) compared to the inactive control group. The largest positive intervention effects on socio-

Table 3
Results of multilevel models: intervention effects (Model 1) on resilience (RS14), depression (RBDI) and social/emotional/behavioural skills (SDQ) and modifying effect of grade on intervention effectiveness (Model 2) among girls.

	RS14		RBDI		SDQ	
	Model 1 Estimate (SE)	Model 2 Estimate (SE)	Model 1 Estimate (SE)	Model 2 Estimate (SE)	Model 1 Estimate (SE)	Model 2 Estimate (SE)
Baseline						
Intercept	**77.219 (0.713)**	**77.307 (0.895)**	**2.121 (0.258)**	**2.323 (0.329)**	**9.730 (0.350)**	**9.895 (0.443)**
Grade 7 vs. 6	0.724 (0.989)	−2.052 (1.701)	0.131 (0.357)	0.281 (0.626)	−0.176 (0.483)	−0.016 (0.837)
Grade 8 vs. 6	**−1.506 (0.753)**	−0.879 (1.190)	**1.035 (0.270)**	0.575 (0.437)	**1.708 (0.368)**	**1.340 (0.587)**
Group (Int vs. 0)	0.089 (1.188)	0.860 (1.968)	−0.656 (0.432)	−0.795 (0.726)	−0.743 (0.584)	−0.182 (0.973)
Group (Int vs. Control)	−0.187 (0.790)	−0.235 (1.293)	0.119 (0.287)	0.744 (0.474)	0.237 (0.389)	0.318 (0.642)
Group (Int vs. 0) × Grade (7 vs. 6)		−4.492 (2.899)		0.601 (1.066)		−0.916 (1.428)
Group (Int vs. Control) × Grade (7 vs. 6)		−2.448 (2.403)		−0.624 (0.883)		0.233 (1.184)
Group (Int vs. 0) × Grade (8 vs. 6)		0.771 (2.883)		0.138 (1.060)		−0.219 (1.426)
Group (Int vs. Control) × Grade (8 vs. 6)		0.780 (1.698)		−1.066 (0.622)		−0.227 (0.841)
Change by 9 weeks						
T9	−0.035 (0.418)	−0.831 (0.665)	**−0.264 (0.131)**	−0.300 (0.213)	**−0.550 (0.182)**	−0.430 (0.286)
Group (Int vs. 0) × T9	0.344 (0.878)	−0.930 (1.575)	0.216 (0.272)	0.176 (0.494)	−0.292 (0.382)	−1.211 (0.665)
Group (Int vs. Control) × T9	**1.301 (0.593)**	−0.031 (0.955)	−0.310 (0.185)	−0.280 (0.302)	−0.356 (0.259)	0.238 (0.412)
Grade (7 vs. 6) × T9		**3.127 (1.315)**		0.197 (0.417)		−0.783 (0.558)
Grade (8 vs. 6) × T9		0.778 (0.894)		0.021 (0.283)		−0.041 (0.381)
Group (Int vs. 0) × Grade (7 vs. 6) × T9		3.592 (2.261)		0.470 (0.709)		0.968 (0.954)
Group (Int vs. Control) × Grade (7 vs. 6) × T9		3.145 (1.851)		0.170 (0.585)		−1.361 (0.786)
Group (Int vs. 0) × Grade (8 vs. 6) × T9		1.583 (2.228)		−0.378 (0.697)		1.017 (0.948)
Group (Int vs. Control) × Grade (8 vs. 6) × T9		1.879 (1.273)		−0.121 (0.402)		−0.827 (0.544)
Change by 26 weeks						
T26	0.861 (0.480)	0.875 (0.782)	**−0.489 (0.154)**	−0.465 (0.245)	**−1.031 (0.216)**	**−0.922 (0.340)**
Group (Int vs. 0) × T26	1.091 (0.981)	2.863 (1.827)	−0.289 (0.313)	−0.552 (0.574)	−0.491 (0.439)	−0.981 (0.785)
Group (Int vs. Control) × T26	0.749 (0.666)	0.003 (1.107)	**−0.493 (0.214)**	−0.705 (0.347)	−0.411 (0.301)	0.316 (0.485)
Grade (7 vs. 6) × T26		1.701 (1.605)		−0.081 (0.503)		−0.507 (0.703)
Grade (8 vs. 6) × T26		−0.444 (1.031)		−0.021 (0.321)		−0.102 (0.447)
Group (Int vs. 0) × Grade (7 vs. 6) × T26		−1.300 (2.643)		0.530 (0.826)		0.535 (1.143)
Group (Int vs. Control) × Grade (7 vs. 6) × T26		1.415 (2.136)		1.062 (0.670)		−0.536 (0.934)
Group (Int vs. 0) × Grade (8 vs. 6) × T26		−1.794 (2.500)		−0.041 (0.781)		0.534 (1.084)
Group (Int vs. Control) × Grade (8 vs. 6) × T26		1.170 (1.451)		0.088 (0.454)		**−1.317 (0.632)**
Variance components						
Student level						
Intercept	**78.095 (3.891)**	**78.145 (3.889)**	**12.241 (0.559)**	**12.220 (0.558)**	**19.623 (0.889)**	**19.624 (0.890)**
T9	0.301 (4.504)	0.188 (4.491)	0.000* (0.000*)	0.000* (0.000*)	0.000* (0.000*)	0.000* (0.000*)
T26	**19.017 (4.844)**	**18.532 (4.815)**	**1.235 (0.441)**	**1.231 (0.440)**	**3.261 (0.725)**	**3.280 (0.725)**
Classroom level						
Intercept	**7.994 (2.309)**	**7.124 (2.208)**	**1.005 (0.304)**	**0.948 (0.297)**	**2.409 (0.619)**	**2.229 (0.599)**
T9	0.437 (1.144)	0.225 (1.114)	0.000* (0.000*)	0.000* (0.000*)	**0.551 (0.269)**	0.388 (0.250)
T26	0.000* (0.000*)	0.000* (0.000*)	0.111 (0.145)	0.029 (0.134)	**0.716 (0.351)**	0.487 (0.323)

Statistically significant ($p < 0.05$) estimates from Wald tests are bolded.
Int = Intervention group (n = 658).
Cont = Active control group (n = 667).
0 = Inactive control group (n = 188).
* Due to convergence problems, the variance was fixed to zero.

emotional functioning were seen in the highest intensity practice group at T9 (−0.41) and T26 (−0.24) compared to the active controls, and at T9 (−0.33) compared to the inactive control group.

5. Discussion

In this large RCT among Finnish adolescents from 56 schools, we found slight positive MBI effects over the relaxation intervention for resilience at the completion of the intervention (T9), and for depressive symptoms among girls at 6 months' follow-up (T26). Positive MBI intervention effects emerged also for all 7th graders in socio-emotional functioning compared to the active control group at follow-up (T9 and T26). Furthermore, children and adolescents who carried out their daily independent mindfulness practice, also demonstrated an increase in resilience at follow-up (T26) compared to the active control group, and improvement in socio-emotional functioning at the completion of the intervention (T9) when compared with the active and inactive control groups. Our results suggest that a short 9 week MBI implemented once a week produce slight mental well-being benefits for the generation of pre- and early adolescents.

This study is, to our knowledge, the first RCT to evaluate the effects of MBI by comparing equal dose and comparable didactic and experiential content, as has been recommended (Felver et al., 2016). Our results are consistent with previous studies, where school-based MBIs have shown positive effects on a variety of psychological measures, e.g., coping, psychological well-being (Huppert and Johnson, 2010; Kuyken et al., 2013), and resilience. MBIs have also demonstrated marked effect on reducing stress and depressive symptoms (Felver et al., 2016; Kuyken et al., 2013; Zenner et al., 2014). This study replicates some of these findings, but goes beyond majority of previous research by comparing the intervention effects to those of the active control group, thus controlling for the possibility that all the intervention effects may not be only mindfulness related. School based socio-emotional interventions are in general found to produce positive impact in a variety of measures. Our findings of stronger effects on mental wellbeing among those carrying out higher intensity mindfulness practice is also in line with increasing – though still somewhat contradicting – evidence on the benefits of regular, sustained mindfulness practice in adults (Carmody and Baer, 2008) and in adolescents. In addition, it indicates that the benefits for increased wellbeing and decreased mental ill-health,

Table 4
Results of multilevel models: Intervention effects (Model 1) on resilience (RS14), depression (RBDI) and social/emotional/behavioural skills (SDQ) and modifying effect of grade on intervention effectiveness (Model 2) among boys.

	RS14		RBDI		SDQ	
	Model 1 Estimate (SE)	Model 2 Estimate (SE)	Model 1 Estimate (SE)	Model 2 Estimate (SE)	Model 1 Estimate (SE)	Model 2 Estimate (SE)
Baseline						
Intercept	**77.546 (0.669)**	**78.728 (0.814)**	**1.684 (0.174)**	**1.452 (0.224)**	**9.982 (0.337)**	**9.599 (0.404)**
Grade 7 vs. 6	0.118 (0.945)	−1.342 (1.634)	0.074 (0.232)	0.480 (0.455)	0.311 (0.493)	0.972 (0.808)
Grade 8 vs. 6	−0.339 (0.726)	**−2.424 (1.100)**	−0.016 (0.177)	0.364 (0.304)	0.693 (0.380)	**1.305 (0.546)**
Group (Int vs. 0)	0.932 (1.136)	2.336 (1.868)	**0.642 (0.310)**	0.571 (0.529)	0.532 (0.563)	0.423 (0.941)
Group (Int vs. Control)	0.509 (0.755)	**3.123 (1.196)**	0.054 (0.206)	−0.330 (0.331)	−0.031 (0.372)	−0.984 (0.598)
Group (Int vs. 0) × Grade (7 vs. 6)		−1.402 (2.765)		0.289 (0.774)		−0.046 (1.381)
Group (Int vs. Control) × Grade (7 vs. 6)		−2.518 (2.242)		0.948 (0.626)		1.672 (1.115)
Group (Int vs. 0) × Grade (8 vs. 6)		−3.048 (2.745)		−0.031 (0.768)		0.697 (1.374)
Group (Int vs. Control) × Grade (8 vs. 6)		**−4.805 (1.606)**		0.517 (0.444)		1.462 (0.801)
Change by 9 weeks						
T9	−0.722 (0.552)	−0.595 (0.849)	−0.196 (0.138)	−0.055 (0.218)	0.340 (0.262)	0.399 (0.407)
Group (Int vs. 0) × T9	**−2.558 (1.176)**	−3.923 (2.070)	−0.274 (0.292)	−0.353 (0.530)	0.460 (0.558)	−0.403 (0.997)
Group (Int vs. Control) × T9	1.036 (0.796)	0.856 (1.239)	0.002 (0.200)	0.091 (0.320)	−0.460 (0.379)	−0.299 (0.598)
Grade (7 vs. 6) × T9		1.859 (1.735)		−0.171 (0.446)		−0.302 (0.825)
Grade (8 vs. 6) × T9		−0.774 (1.154)		−0.253 (0.295)		−0.061 (0.552)
Group (Int vs. 0) × Grade (7 vs. 6) × T9		4.816 (2.980)		0.040 (0.760)		0.729 (1.426)
Group (Int vs. Control) × Grade (7 vs. 6) × T9		0.579 (2.398)		−0.582 (0.618)		−1.147 (1.148)
Group (Int vs. 0) × Grade (8 vs. 6) × T9		0.044 (2.949)		0.201 (0.750)		1.669 (1.413)
Group (Int vs. Control) × Grade (8 vs. 6) × T9		0.311 (1.682)		0.006 (0.433)		0.005 (0.807)
Change by 26 weeks						
T26	**−1.516 (0.643)**	**−2.630 (1.012)**	−0.081 (0.234)	0.079 (0.382)	0.365 (0.300)	0.351 (0.462)
Group (Int vs. 0) × T26	−2.381 (1.298)	−3.715 (2.463)	−0.169 (0.464)	0.028 (0.856)	0.785 (0.597)	0.430 (1.099)
Group (Int vs. Control) × T26	−0.711 (0.904)	−2.028 (1.448)	−0.078 (0.332)	−0.030 (0.547)	0.138 (0.421)	0.769 (0.661)
Grade (7 vs. 6) × T26		3.572 (2.320)		0.344 (0.855)		−1.776 (1.085)
Grade (8 vs. 6) × T26		1.515 (1.353)		−0.356 (0.500)		0.302 (0.614)
Group (Int vs. 0) × Grade (7 vs. 6) × T26		4.362 (3.632)		−0.021 (1.297)		−1.303 (1.652)
Group (Int vs. Control) × Grade (7 vs. 6) × T26		2.768 (2.939)		0.266 (1.092)		−2.257 (1.360)
Group (Int vs. 0) × Grade (8 vs. 6) × T26		1.334 (3.344)		0.123 (1.184)		0.791 (1.495)
Group (Int vs. Control) × Grade (8 vs. 6) × T26		2.287 (1.948)		−0.097 (0.724)		−0.952 (0.884)
Variance components						
Student level						
Intercept	**76.530 (4.198)**	**76.449 (4.194)**	**5.862 (0.338)**	**5.866 (0.337)**	**20.140 (1.035)**	**20.099 (1.034)**
T9	**38.034 (6.056)**	**38.244 (6.058)**	0.000* (0.000*)	0.000* (0.000*)	**4.963 (1.270)**	**5.021 (1.273)**
T26	**61.475 (6.967)**	**61.199 (6.959)**	**3.881 (0.555)**	**3.882 (0.554)**	**6.247 (1.327)**	**6.311 (1.330)**
Classroom level						
Intercept	**6.417 (2.370)**	**5.322 (2.244)**	0.192 (0.172)	0.161 (0.168)	**1.396 (0.574)**	**1.250 (0.557)**
T9	**6.007 (2.597)**	4.789 (2.456)	0.062 (0.161)	0.050 (0.159)	**1.602 (0.585)**	**1.391 (0.562)**
T26	**6.907 (3.214)**	**6.498 (3.165)**	**1.671 (0.432)**	**1.671 (0.432)**	**2.010 (0.690)**	**1.646 (0.647)**

Statistically significant ($p < 0.05$) estimates from Wald tests are bolded.
Int = Intervention group (n = 675).
Cont = Active control group (n = 623).
0 = Inactive control group (n = 182).
* Due to convergence problems, the variance was fixed to zero.

indeed, are related to mindfulness (Durlak et al., 2011).

These findings suggest that mindfulness practice may be effective in improving resilience, i.e., the capacity to recover from difficulties, also in children and adolescents. Our results suggests that maintenance and strengthening of the effect requires regular practice. In our study, students reporting nearly daily practice at the 26 weeks follow-up showed 4 points increase in resilience scores (online Supplementary Table S2). Interestingly, of those 43 students with a 4 point increase at the 26 week follow-up 34 (79%) were boys. In other words, these tentative findings suggest that MBI appears also to benefit boys in resilience but they might require more regular practice compared to girls.

This study strengthens the evidence that MBI ameliorates depressive symptoms, or low-grade depression (Biegel et al., 2009; Kuyken et al., 2013). In our study, this effect was present only among girls. The lack of effect among boys may be explained by lower baseline levels in depressive symptoms (Table 2 'floor effect'). Gender differences in the development of depression are highlighted from pre- and early adolescence on (Hosseinpoor et al., 2012), since depression and its symptoms are twice as prevalent in adolescent girls and adult women (Gater et al., 1998); the difference has been associated with hormonal changes (Rojiani et al., 2017), other biological, psychological, and cultural factors (Altemus et al., 2014; Mendelson et al., 2010). In addition, several previous studies have shown ruminative thought pattern to be associated with higher risk of depression (Spasojevic and Alloy, 2001), and studies have suggested MBI to decrease rumination both among adults (Heeren and Philippot, 2011; Jain et al., 2007) and youth (Mendelson et al., 2010). Therefore, it has been suggested that MBI may produce better results for women by decreasing rumination, which targets women's tendencies toward an internalized distress response (Rojiani et al., 2017).

Concerning socio-emotional functioning, positive intervention effect was detected only among 7th graders (13-years olds). Therefore, our findings provide a preliminary indication that MBI may protect well-being after school transitions; among seventh graders the MBI showed a statistically significant positive effect in socio-emotional functioning compared to the active control group. Finnish students change school from primary to secondary between sixth and seventh grade and school transition is a known risk factor for well-being (Benner, 2011; West et al., 2010). The present study supports the assumption of the effectiveness of socio-emotional programs in class (Bloyce, 2012).

The intervention dose had a positive effect on socio-emotional functioning in MBI group. Adolescents who reported having practiced nearly daily at 26 weeks of follow-up showed over a 2 points improvement in socio-emotional functioning at the 9 weeks follow-up (online Supplementary Table S2).

Based on these results, providing a MBI program evokes slightly more beneficial effects compared to a relaxation program. However, it is evident that the effect of 9 lessons of MBI in the school context can only yield modest results. Compared to some other previous studies, the effects detected here were more modest, which may be partially due to more rigorous methodology of this trial. Interestingly, MBIs delivered during late adolescence (15–18) have been reported to produce greater effect on mental health and well-being compared to younger age groups (Carsley et al., 2018). In order for the pre- and early adolescents to experience mindfulness and health benefits, research on further adaptations to the existing mindfulness interventions for students in earlier stages might be required (Burke, 2010; Zoogman et al., 2014). Furthermore, future trials should invest in process evaluation to shed light on mechanisms of lack of effects and on the most optimal ways to adapt and deliver MBI in school context.

6. Strengths and limitations

To the best of our knowledge, the current study (Volanen et al., 2016) is one of the most methodologically rigorous research projects in the area of school-based MBI. It is a school-based RCT including an active and inactive control group of around 3500 12–15 year old adolescents with a follow-up up to 26 weeks. Wide-ranging characteristics of students and school district are also included. Classroom and school effect have been statistically accounted for and the trial utilizes existing manualized MBI (Stop and Breathe .b), as well as three diverse outcomes. Professional mindfulness facilitators implemented the intervention. To avoid the risk of contamination, randomization was conducted at the school level.

Our study was implemented following the protocol as closely as possible. However, separate analyses for the amount of independent practice was not included as pre-planned analyses in the protocol. Since there is quite few research on this topic, and some contradiction regarding the results, we decided that it was appropriate to deviate from the protocol in this part. The number of participants was reduced by the drop outs (online Supplementary Table S4), however, this was comparable to similar trials. The inactive control group was smaller than the intervention and active control groups, which reduces statistical power and increases the probability of the type-II-errors.

7. Conclusion

This first large-scale RCT showed that a short 9-week school-based MBI taught once a week is a slightly more effective in increasing mental well-being among 12–15 year old children and adolescents compared to relaxation program and teaching as usual. Future studies should examine whether classroom teacher delivery of MBI along with regular mindfulness practice in the long run can strengthen these effects. As the effects of MBI appear to differ by gender and grade, we suggest that further research examining these differences is needed.

Declaration of Competing Interest

None.

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Supplementary material

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jad.2019.08.087.

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